



10023352

NOV 22 2002

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: _____."

Submitter: Maine Standards Company
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Windham, ME 04062
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Contact: Christine Beach, Mgr. RA/QA

Summary prepared on: September 30, 2002

Proprietary Name: VALIDATE Chem 9 Calibration Verification Test Set
Common Name: Calibration Verification
Classification Name: Calibrator, Multi-Analyte

Predicate Devices:

1. **DOCUMENT** Serum Multi-Analyte CAL-VER, K950469, manufactured by CASCO NERL Diagnostics.
2. Ortho-Clinical Diagnostics VITROS Calibrator Kit 1

Device description: VALIDATE Chem 9 Calibration Verification Test Set contains purified chemicals in a protein matrix. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains one bottle each of five (5) levels. Each bottle contains 5 milliliters.

Intended use: VALIDATE Chem 9 Calibration Verification Test Set is intended for *in vitro* diagnostic use for quantitatively verifying calibration, validating reportable ranges, and determining linearity for automated and manual chemistry systems for the following eighteen analytes: albumin (ALB), calcium (CA), cholesterol (CHOL), chloride (CL), carbon dioxide (CO₂), creatinine (CRE), glucose (GLU), iron (FE), lactate (LAC), lithium (LI), magnesium (MG), phosphorus (PO₄), potassium (K), sodium (NA), total protein (TP), triglyceride (TRIG), urea nitrogen (BUN), and uric acid (UA).

Comparison of VALIDATE Chem 9 Calibration Verification Test Set to the predicate devices:

Table 1 compares characteristics of the VALIDATE Chem 9 Calibration Verification Test Set with those of the DOCUMENT Serum Multi-Analyte CAL•VER and Ortho-Clinical Diagnostics VITROS Calibrator Kit 1.

TABLE 1. Comparison of Products

	VALIDATE CHEM 9 Calibration Verification Test Set	DOCUMENT Serum Multi-Analyte CAL•VER	Ortho-Clinical Diagnostics VITROS Calibrator Kit 1
Catalog #	109	M-115	1882208
Intended Use	For <i>in vitro</i> diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For use in the calibration of VITROS chemistry systems for the quantitative measurement of lactate.
Analytes	ALB, CA, CHOL, CL, CO2, CREAT, GLU, FE, LAC, LITH, MG, PO4, K, NA, TPROT, TRIG, BUN, URIC ACID	ALB, CA, CHOL, CL, CO2, CREAT, GLU, FE, LITH, MG, PO4, K, NA, TPROT, TRIG, BUN, URIC ACID	LAC
Matrix	Bovine serum albumin	Human serum	Bovine serum albumin
Number of Levels	5	5	3
Preparation	Liquid, ready to use	Liquid, ready to use	Lypholized
Packaging	5.0 mL each level	2 x 3.0 mL each level	3.0 mL each level
Stability	9 months	9 months	24 hours after reconstitution
Storage	-10 to -20°C	-10 to -20°C	-10 to -20°C

The performance of VALIDATE Chem 9 Calibration Verification Test Set solutions on the VITROS instrument system as compared to DOCUMENT Serum Multi-Analyte CAL•VER and Ortho-Clinical Diagnostics VITROS Calibrator Kit 1 been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 9 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 9 Calibration Verification Test Set and the predicate devices are presented in Table 2.

TABLE 2. Linear Regression Statistical Comparison of VALIDATE Chem 9 Calibration Verification Test Set to the predicate devices.

Analyte	VALIDATE Chem 9 Calibration Verification Test Set		DOCUMENT Serum Multi-Analyte CAL•VER	
	Correlation Coefficient (r)	Regression Equation $Y = \text{slope}(X) + \text{intercept}$	Correlation Coefficient (r)	Regression Equation $Y = \text{slope}(X) + \text{intercept}$
ALB	0.9942	$x - 0.1$	0.998	$0.997x + 0.022$
BUN	0.9999	$1.0138x - 0.4276$	0.999	$1.005x + 0.618$
CA	0.9974	$1.01x + 0.288$	0.999	$0.995x + 0.035$
CHOL	0.9999	$0.9935x + 1.8102$	0.995	$1.058x - 6.192$
CL	0.9996	$0.9581x + 3.6226$	0.998	$1.010x - 1.389$
CO2	0.9971	$0.875x + 1.675$	0.998	$1.009x - 0.176$
CRE	0.9986	$0.9364 + 0.1791$	0.999	$0.974x + 0.073$
FE	0.9988	$0.9205x + 14.617$	0.998	$1.119x - 14.492$
GLU	0.9999	$1.0132x - 0.7707$	0.999	$1.050x - 9.370$
K	0.9987	$0.9984x - 0.2576$	0.999	$0.983 + 0.170$
LITH	0.9997	$0.9733x + 0.0187$	0.994	$0.924x + 0.015$
MG	0.9993	$0.9832 + 0.1053$	0.998	$1.051x - 0.082$
NA	0.9991	$1.0042x + 1.8979$	0.998	$1.076x - 7.561$
PO4	0.9998	$0.975x + 0.035$	0.999	$0.992x + 0.093$
TP	0.9986	$1.097x - 0.5097$	0.998	$1.086x - 0.261$
TRIG	0.9999	$1.0226x - 3.6259$	0.999	$1.018x + 2.292$
URIC ACID	0.9997	$0.97x + 0.161$	0.999	$0.992x + 0.040$

Analyte	VALIDATE Chem 9 Calibration Verification Test Set		Ortho-Clinical Diagnostics VITROS Calibrator Kit 1	
	Correlation Coefficient (r)	Regression Equation $Y = \text{slope}(X) + \text{intercept}$	Correlation Coefficient (r)	Regression Equation $Y = \text{slope}(X) + \text{intercept}$
LAC	1.0000	$1.012x - 0.0272$	0.9995	$0.9398x + 0.0692$

Summary:

Linear regression analysis was carried out on recovered values for each analyte. Each analyte was tested in triplicate. The VALIDATE Chem 9 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Serum Multi-Analyte CAL•VER and Ortho-Clinical Diagnostics VITROS Calibrator Kit 1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 22 2002

Ms. Christine Beach
Manager, RA/QA
Maine Standards Company
765 Roosevelt Trail – Suite 9A
Windham, ME 04062

Re: k023352
Trade/Device Name: Validate Chem 9 Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 30, 2002
Received: October 7, 2002

Dear Ms. Beach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

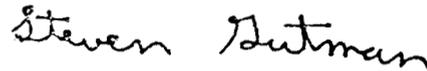
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

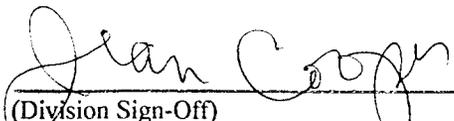
INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Validate Chem 9 Calibration Verification Test Set

Indications for Use:

The VALIDATE Chem 9 Calibration Verification Test Set is used by trained laboratory professionals for the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated, and manual clinical chemistry systems for the following eighteen analytes: albumin, calcium, cholesterol, chloride, carbon dioxide, creatinine, glucose, iron, lactate, lithium, magnesium, phosphorus, potassium, sodium, total protein, triglyceride, urea nitrogen, and uric acid.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023352

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use